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12 UNITED STATES DISTRICT COURT
13 DISTRICT OF ARIZONA

14 Edward Finck, a single man,
15
16 Plaintiff,

17 v.

18 Pfizer, Inc., a Delaware corporation with its
19 principal place of business in New York;
20 Pharmacia Corporation, a Delaware
21 corporation with its principal place of business
22 in New Jersey; Monsanto Co., a subsidiary of
23 Pharmacia and a Delaware corporation with its
24 principal place of business in Missouri; G.D.
25 Searle & Company, a Delaware corporation
26 with its principal place of business in Illinois,

Defendants.

No. CV 06-3017-PHX-JAT

ANSWER

(Jury Trial Requested)

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COME Defendants Pfizer Inc. (incorrectly captioned in Plaintiff's
Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a "Monsanto

1 Company”¹) (“Pharmacia”), and G.D. Searle LLC (improperly captioned in Plaintiff’s
2 Complaint as “G.D. Searle & Company”) (“Searle”), collectively “Defendants,” and file
3 this their Original Answer to Plaintiff’s Complaint (“Complaint”), and would respectfully
4 show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or
8 used Celebrex®. Accordingly, this Answer can only be drafted generally. Defendants
9 may seek leave to amend this Answer when discovery reveals the specific time periods in
10 which Plaintiff was prescribed and used Celebrex®.

11 **II.**

12 **ORIGINAL ANSWER**

13 **Response to Introduction**

14 Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-
15 promoted and marketed Celebrex® in the United States to be prescribed by healthcare
16 providers who are by law authorized to prescribe drugs in accordance with their approval
17 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
18 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
19 and distributed Celebrex® in the United States to be prescribed by healthcare providers

20
21 ¹ Plaintiff’s Complaint names “Monsanto Company” as a defendant. Defendants
22 state that in 1933, an entity known as Monsanto Company (“1933 Monsanto”) was
23 incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed
24 its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto
25 Ag Company, was incorporated under the laws of Delaware. On March 31, 2000,
26 Monsanto Ag Company changed its name to Monsanto Company (“2000 Monsanto”).
The 2000 Monsanto is engaged in the agricultural business and does not and has not ever
designed, produced, manufactured, sold, resold or distributed Celebrex®. Given that
Plaintiff alleges in his Complaint that Monsanto Company was involved in developing
Celebrex®, *see* PLAINTIFF’S COMPLAINT at ¶ 4, Defendants assume Plaintiff means to
refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at
Monsanto Company.

1 who are by law authorized to prescribe drugs in accordance with their approval by the
2 FDA. Defendants state that Celebrex® is and was safe and effective when used in
3 accordance with its FDA-approved prescribing information. As for the allegations in this
4 paragraph of the Complaint regarding the NCI study, Defendants state that the referenced
5 study speaks for itself and respectfully refer the Court to the study for its actual language
6 and text. Any attempt to characterize the study is denied. Defendants deny that
7 Celebrex® is defective and deny the remaining allegations in the first unnumbered
8 paragraph of the Complaint.

9 **Response to Allegations Regarding Jurisdiction and Venue**

10 1. Defendants are without knowledge or information sufficient to form a basis
11 as to the truth of the allegations concerning the Plaintiff's citizenship, and therefore deny
12 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 2. Defendants are without knowledge or information sufficient to form a basis
14 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
15 deny the same. Defendants admit that, during certain periods of time, Pfizer and
16 Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by
17 healthcare providers who are by law authorized to prescribe drugs in accordance with
18 their approval by the FDA. Defendants admit that, during certain periods of time,
19 Celebrex® was manufactured and packaged for Searle, which developed, tested,
20 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
21 healthcare providers who are by law authorized to prescribe drugs in accordance with
22 their approval by the FDA. Defendants deny the remaining allegations contained in this
23 paragraph of the Complaint.

24 3. Defendants admit that Pharmacia is a Delaware corporation with its
25 principal place of business in the State of New Jersey, and that Pharmacia does business in
26 Arizona. Defendants admit that, during certain periods of time, Pharmacia marketed and

1 co-promoted Celebrex® throughout the United States to be prescribed by healthcare
2 providers who are authorized by law to prescribe drugs in accordance with their approval
3 by the FDA. Defendants deny the remaining allegations contained in this paragraph of the
4 Complaint.

5 4. Defendants admit that in 1933 an entity known as Monsanto Company
6 (“1933 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a
7 subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto
8 changed its name to Pharmacia Corporation. On February 9, 2000, a separate company,
9 Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31,
10 2000, Monsanto Ag Company changed its name to Monsanto Company (“2000
11 Monsanto”). The 2000 Monsanto is engaged in the agricultural business and does not and
12 has not ever designed, produced, manufactured, sold, resold, or distributed Celebrex®.
13 The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia.
14 As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold,
15 resold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not
16 a proper party in this matter. Defendants deny the remaining allegations contained in this
17 paragraph of the Complaint. Defendants state that the response to this paragraph of the
18 Complaint regarding Monsanto is incorporated by reference in each and every paragraph
19 of the Complaint referring to Monsanto and/or Defendants.

20 5. Defendants admit that Pfizer is a Delaware corporation with its principal
21 place of business in New York. Defendants admit that, during certain periods of time,
22 Pfizer co-promoted and marketed the prescription drug Celebrex® in the United States,
23 including Arizona, to be prescribed by healthcare providers who are by law authorized to
24 prescribe drugs in accordance with their approval by the FDA. Defendants admit that as a
25 result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants
26 deny the remaining allegations contained in this paragraph of the Complaint.

1 6. Defendants admit that Searle is a Delaware limited liability company with
2 its principal place of business in Illinois. Pfizer Defendants also admit that, during certain
3 periods of time, Celebrex® was manufactured and packaged for Searle, which developed,
4 tested, marketed, co-promoted and distributed Celebrex® in the United States, including
5 Arizona, to be prescribed by healthcare providers who are by law authorized to prescribe
6 drugs in accordance with their approval by the FDA. Defendants deny the remaining
7 allegations contained in Paragraph 6 of the Complaint.

8 7. Defendants are without knowledge or information sufficient to form a belief
9 as to the truth of the allegations concerning the amount in controversy, and therefore deny
10 the same. However, Defendants admit that Plaintiff claims that the amount in controversy
11 exceeds \$75,000, exclusive of interests and costs. Defendants are without knowledge or
12 information sufficient to form a belief as to the judicial district in which the asserted
13 claims allegedly arose and therefore denies that venue is proper in this district pursuant to
14 28 U.S.C. § 1391. Defendants further deny committing a tort within the State of Arizona
15 and deny the remaining allegations in this paragraph of the Complaint.

16 **Response to General Allegations**

17 8. Defendants are without knowledge or information sufficient to form a basis
18 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
19 deny the same. Defendants admit that, during certain periods of time, Pfizer and
20 Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by
21 healthcare providers who are by law authorized to prescribe drugs in accordance with
22 their approval by the FDA. Defendants admit that, during certain periods of time,
23 Celebrex® was manufactured and packaged for Searle, which developed, tested,
24 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
25 healthcare providers who are by law authorized to prescribe drugs in accordance with
26 their approval by the FDA. Defendants state that Celebrex® was and is safe and effective

1 when used in accordance with its FDA-approved prescribing information. Defendants
2 state that the potential effects of Celebrex® were and are adequately described in its FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
5 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this
6 paragraph of the Complaint.

7 9. Defendants deny any wrongful conduct, deny that Celebrex® caused
8 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
9 Complaint.

10 10. Defendants are without knowledge or information sufficient to form a basis
11 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
12 deny the same. Defendants state that Plaintiff's allegations regarding "successor in
13 interest" are vague and ambiguous. Defendants are without knowledge or information to
14 form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants
15 admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and
16 marketed Celebrex® in the United States to be prescribed by healthcare providers who are
17 by law authorized to prescribe drugs in accordance with their approval by the FDA.
18 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
19 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
20 Celebrex® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
22 deny the remaining allegations in this paragraph of the Complaint.

23 11. Defendants admit that Pfizer, Pharmacia, and Searle are registered to do
24 business in Arizona. Defendants deny the remaining allegations in this paragraph of the
25 Complaint.

1 12. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
2 co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare
3 providers who are by law authorized to prescribe drugs in accordance with their approval
4 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
5 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
6 and distributed Celebrex® in the United States to be prescribed by healthcare providers
7 who are by law authorized to prescribe drugs in accordance with their approval by the
8 FDA. Defendants state that Celebrex® was and is safe and effective when used in
9 accordance with its FDA-approved prescribing information. Defendants state that the
10 potential effects of Celebrex® were and are adequately described in its FDA-approved
11 prescribing information, which was at all times adequate and comported with applicable
12 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex®
13 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of
14 the Complaint.

15 13. This paragraph of the Complaint contains legal conclusions to which no
16 response is required. To the extent that a response is deemed required, Defendants are
17 without knowledge or information sufficient to form a basis as to the truth of the
18 allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same.
19 Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects
21 of Celebrex® were and are adequately described in its FDA-approved prescribing
22 information, which was at all times adequate and comported with applicable standards of
23 care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
24 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
25 Complaint.

1 14. Defendants are without knowledge or information sufficient to form a basis
2 as to the truth of the allegations regarding whether Plaintiff used Celebrex® and whether
3 Plaintiff suffered a myocardial infarction on January 18, 2002, and therefore deny the
4 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Factual Allegations**

6 15. Defendants admit that Celebrex® is in a class of drugs that is, at times,
7 referred to as non-steroidal anti-inflammatory drugs (“NSAIDs”). The remaining
8 allegations in this paragraph of the Complaint are not directed toward Defendants and,
9 therefore, no response is required. To the extent that a response is deemed required,
10 Defendants state that Plaintiff fails to provide the proper context for the remaining
11 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
12 information or knowledge to form a belief as to the truth of such allegations and,
13 therefore, deny the same.

14 16. The allegations in this paragraph of the Complaint are not directed toward
15 Defendants and, therefore, no response is required. To the extent that a response is
16 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
17 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
18 information or knowledge to form a belief as to the truth of such allegations and,
19 therefore, deny the same.

20 17. The allegations in this paragraph of the Complaint are not directed toward
21 Defendants and, therefore, no response is required. To the extent that a response is
22 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
23 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
24 information or knowledge to form a belief as to the truth of such allegations and,
25 therefore, deny the same.

1 18. The allegations in this paragraph of the Complaint are not directed toward
2 Defendants and, therefore, no response is required. To the extent that a response is
3 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
4 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
5 information or knowledge to form a belief as to the truth of such allegations and,
6 therefore, deny the same.

7 19. The allegations in this paragraph of the Complaint are not directed toward
8 Defendants and, therefore, no response is required. To the extent that a response is
9 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
10 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
11 information or knowledge to form a belief as to the truth of such allegations and,
12 therefore, deny the same.

13 20. The allegations in this paragraph of the Complaint are not directed toward
14 Defendants and, therefore, no response is required. To the extent that a response is
15 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
16 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
17 information or knowledge to form a belief as to the truth of such allegations and,
18 therefore, deny the same.

19 21. The allegations in this paragraph of the Complaint are not directed toward
20 Defendants and, therefore, no response is required. To the extent that a response is
21 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
22 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
23 information or knowledge to form a belief as to the truth of such allegations and,
24 therefore, deny the same.

25 22. The allegations in this paragraph of the Complaint are not directed toward
26 Defendants and, therefore, no response is required. To the extent that a response is

1 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
2 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
3 information or knowledge to form a belief as to the truth of such allegations and,
4 therefore, deny the same.

5 23. Defendants state that, as stated in the FDA-approved labeling for
6 Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of
7 prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at
8 therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1
9 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and effective
10 when used in accordance with its FDA-approved prescribing information. Defendants
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-
12 approved prescribing information, which was at all times adequate and comported with
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny
14 the remaining allegations in this paragraph of the Complaint.

15 24. Defendants deny the allegations in this paragraph of the Complaint.

16 25. Defendants deny the allegations in this paragraph of the Complaint.

17 26. Defendants state that Celebrex® was and is safe and effective when used in
18 accordance with its FDA-approved prescribing information. Defendants state that the
19 potential effects of Celebrex® were and are adequately described in its FDA-approved
20 prescribing information, which was at all times adequate and comported with applicable
21 standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 27. As for the allegations in this paragraph of the Complaint regarding the
24 CLASS study, Defendants state that the study speaks for itself and respectfully refer the
25 Court to the study for its actual language and full text. Any attempt to characterize the
26

1 study is denied. Defendants deny the remaining allegations in this paragraph of the
2 Complaint.

3 28. Defendants state that the referenced study speaks for itself and respectfully
4 refer the Court to the study for its actual language and full text. Any attempt to
5 characterize the study is denied. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 29. Defendants state that referenced the study speaks for itself and respectfully
8 refer the Court to the study for its actual language and full text. Any attempt to
9 characterize the study is denied. Defendants deny the remaining allegations in this
10 paragraph of the Complaint.

11 30. Defendants admit that the CLASS study results were provided to the FDA
12 ADA Committee and deny the remaining allegations in this paragraph of the Complaint.

13 31. As for the allegations in this paragraph of the Complaint regarding the
14 CLASS study, Defendants state that the referenced study speaks for itself and respectfully
15 refer the Court to the study for its actual language and text. Any attempt to characterize
16 the study is denied. As for the allegations in this complaint regarding the findings of the
17 FDA Arthritis Drugs Advisory Committee, Defendants state that the transcripts of the
18 FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully
19 refer the Court to the transcripts for their actual language and text. Any attempt to
20 characterize the transcripts is denied. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 32. As for the allegations in this paragraph of the Complaint regarding the
23 CLASS study, Defendants state that the referenced study speaks for itself and respectfully
24 refer the Court to the study for its actual language and text. Any attempt to characterize
25 the study is denied. As for the allegations in this complaint regarding the findings of the
26 FDA Arthritis Drugs Advisory Committee, Defendants state that the transcripts of the

1 FDA Arthritis Drugs Advisory Committee hearings speaks for themselves and
2 respectfully refer the Court to the transcripts for their actual language and text. Any
3 attempt to characterize the transcripts is denied. Defendants deny the remaining
4 allegations in this paragraph of the Complaint.

5 33. Defendants state that Celebrex® was and is safe and effective when used in
6 accordance with its FDA-approved prescribing information. Defendants state that the
7 potential effects of Celebrex® were and are adequately described in its FDA-approved
8 prescribing information, which at all times was adequate and comported with applicable
9 standards of care and law. Defendants deny the allegations in this paragraph of the
10 Complaint.

11 34. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
12 co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare
13 providers who are by law authorized to prescribe drugs in accordance with their approval
14 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
15 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
16 and distributed Celebrex® in the United States to be prescribed by healthcare providers
17 who are by law authorized to prescribe drugs in accordance with their approval by the
18 FDA. Defendants state that Celebrex® was and is safe and effective when used in
19 accordance with its FDA-approved prescribing information. Defendants state that the
20 potential effects of Celebrex® were and are adequately described in its FDA-approved
21 prescribing information, which was at all times adequate and comported with applicable
22 standards of care and law. Defendants deny any wrongful conduct and deny the
23 remaining allegations in this paragraph of the Complaint.

24 35. Defendants admit that Searle submitted a New Drug Application (“NDA”)
25 for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA
26

1 granted approval of the NDA for Celebrex® submitted by Searle on June 29, 1998.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 36. Defendants admit that Searle submitted an NDA for Celebrex® on June 29,
4 1998. Defendants admit that on December 31, 1998, the FDA approved Celebrex® for
5 the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and
6 (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants
7 admit that Celebrex® was released for sale in the United States in February 1999.
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 37. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
10 co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare
11 providers who are by law authorized to prescribe drugs in accordance with their approval
12 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
13 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted,
14 and distributed Celebrex® in the United States to be prescribed by healthcare providers
15 who are by law authorized to prescribe drugs in accordance with their approval by the
16 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 38. Defendants deny the allegations in this paragraph of the Complaint.

18 39. As for the allegations in this paragraph of the Complaint regarding the
19 CLASS study, Defendants state that the referenced study speaks for itself and respectfully
20 refer the Court to the study for its actual language and text. Any attempt to characterize
21 the study is denied. As for the allegations in this Paragraph of the Complaint regarding an
22 article published in the September 13, 2000 issue of JAMA, Defendants state that the
23 referenced article speaks for itself and respectfully refer the Court to the article for its
24 actual language and text. Any attempt to characterize the article is denied. Defendants
25 admit that, before approving a drug, the FDA must conclude that a drug is safe and
26

1 effective when used in accordance with its FDA-approved prescribing information.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 40. Defendants state that the referenced study speaks for itself and respectfully
4 refer the Court to the study for its actual language and text. Any attempt to characterize
5 the study is denied. Defendants deny the remaining allegations in this paragraph of the
6 Complaint.

7 41. As for the allegations in this paragraph of the Complaint regarding the
8 CLASS study, Defendants state that the referenced study speaks for itself and respectfully
9 refer the Court to the study for its actual language and text. Any attempt to characterize
10 the study is denied. As for the allegations in this Paragraph of the Complaint regarding
11 the JAMA article, Defendants state that the referenced article speaks for itself and
12 respectfully refer the Court to the article for its actual language and text. Any attempt to
13 characterize the article is denied. Plaintiffs fail to provide the proper context for the
14 allegations in this paragraph of the Complaint regarding “data on the FDA’s website.”
15 Defendants lack sufficient information or knowledge to form a belief as to the truth of
16 such allegations and therefore deny the same. Defendants deny the remaining allegations
17 in this paragraph of the Complaint.

18 42. Defendants state that the referenced submission speaks for itself and
19 respectfully refer the Court to the submission for its actual language and text. Any
20 attempt to characterize the submission is denied. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 43. As for the allegations in this Paragraph of the Complaint regarding the
23 Medical Officer’s Review, Defendants state that the Medical Officer’s Review speaks for
24 itself and respectfully refer the Court to the Medical Officer’s Review for its actual
25 language and text. Any attempt to characterize the Medical Officer’s Review is denied.
26 As for the allegations in this Paragraph of the Complaint regarding the “JAMA article”,

1 Defendants state that the referenced article speaks for itself and respectfully refer the
2 Court to the article for its actual language and text. Any attempt to characterize the article
3 is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 44. As for the allegations in this paragraph of the Complaint regarding the
5 CLASS study, Defendants state that the referenced study speaks for itself and respectfully
6 refer the Court to the study for its actual language and text. Any attempt to characterize
7 the study is denied. As for the allegations in this Paragraph of the Complaint regarding
8 the “article published in JAMA”, Defendants state that the referenced article speaks for
9 itself and respectfully refer the Court to the article for its actual language and text. Any
10 attempt to characterize the article is denied. As for the allegations in this Paragraph of the
11 Complaint regarding the Medical Officer’s Review, Defendants state that the Medical
12 Officer’s Review speaks for itself and respectfully refer the Court to the Medical Officer’s
13 Review for its actual language and text. Any attempt to characterize the Medical
14 Officer’s Review is denied. Plaintiffs fail to provide the proper context for the allegations
15 in this paragraph of the Complaint regarding “the FDA’s files.” Defendants lack
16 sufficient information or knowledge to form a belief as to the truth of such allegations and
17 therefore deny the same. Defendants deny the remaining allegations in this paragraph of
18 the Complaint.

19 45. Defendants state that the referenced study speaks for itself and respectfully
20 refer the Court to the study for its actual language and text. Any attempt to characterize
21 the study is denied. Defendants state that the referenced article speaks for itself and
22 respectfully refer the Court to the article for its actual language and text. Any attempt to
23 characterize the article is denied. Defendants deny the remaining allegations in this
24 paragraph of the Complaint.

25 46. Defendants state that the referenced study speaks for itself and respectfully
26 refer the Court to the study for its actual language and text. Any attempt to characterize

1 the study is denied. Defendants deny the remaining allegations in this paragraph of the
2 Complaint.

3 47. Defendants admit that the FDA Division of Drug Marketing, Advertising
4 and Communications sent Searle a letter dated July 16, 1997. Defendants respectfully
5 refer the Court to the letter for its actual language and full text. Any attempt to
6 characterize the letter is denied. Defendants respectfully refer the Court to the letters for
7 their actual language and full text. Any attempt to characterize the letters is denied.
8 Defendants admit that the FDA sent letters to Searle dated October 6, 1999, April 6, 2000
9 and November 14, 2000. Defendants respectfully refer the Court to the letters for their
10 actual language and full text. Any attempt to characterize the letters is denied.
11 Defendants admit that the FDA sent a letter to Pharmacia dated February 1, 2001, and that
12 the FDA sent a letter to Pfizer dated January 10, 2005. Defendants respectfully refer the
13 Court to the letters for their actual language and full text. Any attempt to characterize the
14 letters is denied. Defendants deny the remaining allegations in this paragraph of the
15 Complaint.

16 48. Defendants state that the referenced letter speaks for itself, and respectfully
17 refer the Court to the letter for its actual language and text. Any attempt to characterize
18 the letter is denied. Defendants deny the remaining allegations in this paragraph of the
19 Complaint.

20 49. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
21 co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare
22 providers who are by law authorized to prescribe drugs in accordance with their approval
23 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
24 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
25 and distributed Celebrex® in the United States to be prescribed by healthcare providers
26 who are by law authorized to prescribe drugs in accordance with their approval by the

1 FDA. Defendants state that Celebrex® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants state that the
3 potential effects of Celebrex® were and are adequately described in its FDA-approved
4 prescribing information, which was at all times adequate and comported with applicable
5 standards of care and law. Defendants deny the remaining allegations in this paragraph of
6 the Complaint.

7 50. Defendants deny the allegations in this paragraph of the Complaint.

8 51. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
9 co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare
10 providers who are by law authorized to prescribe drugs in accordance with their approval
11 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
12 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
13 and distributed Celebrex® in the United States to be prescribed by healthcare providers
14 who are by law authorized to prescribe drugs in accordance with their approval by the
15 FDA. Defendants state that Celebrex® was and is safe and effective when used in
16 accordance with its FDA-approved prescribing information. Defendants state that the
17 potential effects of Celebrex® were and are adequately described in its FDA-approved
18 prescribing information, which was at all times adequate and comported with applicable
19 standards of care and law. Defendants state that as indicated in the package insert
20 approved by the FDA, Celebrex® has been approved by the FDA for the following
21 indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the
22 signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute
23 pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of
24 adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to
25 usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of
26 ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile

1 rheumatoid arthritis in patients two years of age and older. Defendants deny the
2 remaining allegations in this paragraph of the Complaint.

3 52. To the extent that the allegations in this paragraph of the Complaint are not
4 directed at Defendants, no response is required. To the extent that a response is deemed
5 required, Plaintiffs fail to provide the proper context for such allegations. Defendants lack
6 sufficient information or knowledge to form a belief as to the truth of such allegations and
7 therefore deny the same. Defendants admit that, during certain periods of time, Pfizer and
8 Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by
9 healthcare providers who are by law authorized to prescribe drugs in accordance with
10 their approval by the FDA. Defendants admit that, during certain periods of time,
11 Celebrex® was manufactured and packaged for Searle, which developed, tested,
12 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed
13 by healthcare providers who are by law authorized to prescribe drugs in accordance with
14 their approval by the FDA. Defendants deny the remaining allegations in this paragraph
15 of the Complaint.

16 53. The allegations in this paragraph of the Complaint regarding “other drug
17 companies” are not directed at Defendants, and, therefore, no response is required. To the
18 extent that a response is deemed required, Plaintiffs fail to provide the proper context for
19 the allegations in this paragraph of the Complaint regarding “other drug companies.”
20 Defendants lack sufficient information or knowledge to form a belief as to the truth of
21 such allegations and therefore deny the same. Plaintiffs fail to provide the proper context
22 for the allegations in this paragraph of the Complaint regarding “blockbuster drugs.”
23 Defendants lack sufficient information or knowledge to form a belief as to the truth of
24 such allegations and therefore deny the same. Defendants admit that, during certain
25 periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United
26 States to be prescribed by healthcare providers who are by law authorized to prescribe

1 drugs in accordance with their approval by the FDA. Defendants admit that, during
2 certain periods of time, Celebrex® was manufactured and packaged for Searle, which
3 developed, tested, marketed, co-promoted, and distributed Celebrex® in the United States
4 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in
6 this paragraph of the Complaint.

7 54. Defendants deny any wrongful conduct and deny the remaining allegations
8 in this paragraph of the Complaint.

9 55. Defendants state that Celebrex® was and is safe and effective when used in
10 accordance with its FDA-approved prescribing information. Defendants state that the
11 potential effects of Celebrex® were and are adequately described in its FDA-approved
12 prescribing information, which was at all times adequate and comported with applicable
13 standards of care and law. Defendants deny any wrongful conduct and denies the
14 remaining allegations in this paragraph of the Complaint.

15 56. The allegations in this paragraph of the Complaint are not directed toward
16 Defendants and, therefore, no response is required. To the extent that a response is
17 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
18 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
19 information or knowledge to form a belief as to the truth of such allegations and,
20 therefore, deny the same.

21 57. The allegations in this paragraph of the Complaint are not directed toward
22 Defendants and, therefore, no response is required. To the extent that a response is
23 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
24 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
25 information or knowledge to form a belief as to the truth of such allegations and,
26 therefore, deny the same.

1 58. Defendants state that Celebrex® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants state that the
3 potential effects of Celebrex® were and are adequately described in its FDA-approved
4 prescribing information, which was at all times adequate and comported with applicable
5 standards of care and law. Defendants deny the remaining allegations in this paragraph of
6 the Complaint.

7 59. Defendants state that the referenced study speaks for itself and respectfully
8 refer the Court to the study for its actual language and text. Any attempt to characterize
9 the study is denied. Defendants deny the remaining allegations in this paragraph of the
10 Complaint.

11 60. The allegations in this paragraph of the Complaint are not directed toward
12 Defendants and, therefore, no response is required. To the extent that a response is
13 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
14 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient
15 information or knowledge to form a belief as to the truth of such allegations and,
16 therefore, deny the same.

17 61. Defendants state that Celebrex® was and is safe and effective when used in
18 accordance with its FDA-approved prescribing information. Defendants state that the
19 potential effects of Celebrex® were and are adequately described in its FDA-approved
20 prescribing information, which was at all times adequate and comported with applicable
21 standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 62. Defendants state that the referenced FDA documents speak for themselves
24 and respectfully refer the Court to the documents for their actual language and text. Any
25 attempt to characterize the documents is denied. Defendants deny the remaining
26 allegations this paragraph of the Complaint.

1 63. Defendants admit that the FDA sent a letter to Searle dated October 6, 1999.
2 Defendants respectfully refer the Court to the letter for its actual language and full text.
3 Any attempt to characterize the letter is denied. Defendants deny the remaining
4 allegations in this paragraph of the Complaint.

5 64. Defendants admit that the FDA sent a letter to Searle dated April 6, 2000.
6 Defendants respectfully refer the Court to the letter for its actual language and full text.
7 Any attempt to characterize the letter is denied. Defendants deny the remaining
8 allegations in this paragraph of the Complaint.

9 65. Defendants admit that the FDA sent a letter to Searle dated November 14,
10 2000. Defendants respectfully refer the Court to the letter for its actual language and full
11 text. Any attempt to characterize the letter is denied. Defendants deny the remaining
12 allegations in this paragraph of the Complaint.

13 66. Defendants admit that the FDA sent a letter to Pharmacia dated February 1,
14 2001. Defendants respectfully refer the Court to the letter for its actual language and full
15 text. Any attempt to characterize the letter is denied. Defendants deny the remaining
16 allegations in this paragraph of the Complaint.

17 67. Defendants state that Celebrex® was and is safe and effective when used in
18 accordance with its FDA-approved prescribing information. Defendants state that the
19 potential effects of Celebrex® were and are adequately described in its FDA-approved
20 prescribing information, which was at all times adequate and comported with applicable
21 standards of care and law. Defendants state that the referenced letter speaks for itself and
22 respectfully refer the Court to referenced letter for its actual language and full text. Any
23 attempt to characterize the letter is denied. Defendants deny any wrongful conduct and
24 deny the remaining allegations in this paragraph of the Complaint.

25 68. Defendants state that Celebrex® was and is safe and effective when used in
26 accordance with its FDA-approved prescribing information. Defendants state that the

1 potential effects of Celebrex® were and are adequately described in its FDA-approved
2 prescribing information, which was at all times adequate and comported with applicable
3 standards of care and law. Defendants state that the referenced letter speaks for itself and
4 respectfully refer the Court to referenced letter for its actual language and full text. Any
5 attempt to characterize the letter is denied. Defendants deny any wrongful conduct and
6 deny the remaining allegations in this paragraph of the Complaint.

7 69. As for the allegations in this paragraph of the Complaint regarding
8 advertising and packaging materials, Defendants state that the referenced advertising and
9 packaging materials speaks for themselves and respectfully refer the Court to the
10 advertising and packaging materials for their actual language and text. Any attempt to
11 characterize the advertising and packaging materials is denied. Defendants state that
12 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
13 prescribing information. Defendants state that the potential effects of Celebrex® were
14 and are adequately described in its FDA-approved prescribing information, which at all
15 times was adequate and comported with applicable standards of care and law. Defendants
16 admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and
17 marketed Celebrex® in the United States to be prescribed by healthcare providers who are
18 by law authorized to prescribe drugs in accordance with their approval by the FDA.
19 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
20 packaged for Searle, which developed, tested, marketed, co-promoted, and distributed
21 Celebrex® in the United States to be prescribed by healthcare providers who are by law
22 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
23 deny the remaining allegations in this paragraph of the Complaint.

24 70. Defendants state that the referenced advertising and packaging materials
25 speak for themselves and respectfully refer the Court to the advertising and packaging
26 materials for their actual language and text. Any attempt to characterize the advertising

1 and packaging materials is denied. Defendants state that Celebrex® was and is safe and
2 effective when used in accordance with its FDA-approved prescribing information.
3 Defendants state that the potential effects of Celebrex® were and are adequately described
4 in its FDA-approved prescribing information, which at all times was adequate and
5 comported with applicable standards of care and law. Defendants deny any wrongful
6 conduct and deny the remaining allegations in this paragraph of the Complaint.

7 71. Defendants state that the referenced advertising and packaging materials
8 speaks for themselves and respectfully refer the Court to the advertising and packaging
9 materials for their actual language and text. Any attempt to characterize the advertising
10 and packaging materials is denied. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information.
12 Defendants state that the potential effects of Celebrex® were and are adequately described
13 in its FDA-approved prescribing information, which at all times was adequate and
14 comported with applicable standards of care and law. As for the allegations in this
15 paragraph of the Complaint regarding advertising and packaging materials, Defendants
16 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
17 Complaint.

18 72. Defendants state that the referenced print advertisements speak for
19 themselves and respectfully refer the Court to the print advertisements for their actual
20 language and text. Any attempt to characterize the print advertisements is denied.
21 Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects
23 of Celebrex® were and are adequately described in its FDA-approved prescribing
24 information, which at all times was adequate and comported with applicable standards of
25 care and law. Defendants deny the remaining allegations in this paragraph of the
26 Complaint.

1 73. Defendants state that the referenced print advertisements speak for
2 themselves and respectfully refer the Court to the print advertisements for their actual
3 language and text. Any attempt to characterize the print advertisements is denied.
4 Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects
6 of Celebrex® were and are adequately described in its FDA-approved prescribing
7 information, which at all times was adequate and comported with applicable standards of
8 care and law. Defendants deny the remaining allegations in this paragraph of the
9 Complaint.

10 74. Defendants state that the referenced print advertisement speaks for itself and
11 respectfully refer the Court to the print advertisement for its actual language and text.
12 Any attempt to characterize the print advertisement is denied. Defendants state that
13 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
14 prescribing information. Defendants state that the potential effects of Celebrex® were
15 and are adequately described in its FDA-approved prescribing information, which at all
16 times was adequate and comported with applicable standards of care and law. Defendants
17 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
18 Complaint.

19 **Response to First Cause of Action: Strict Liability – Failure to Warn**

20 75. Defendants incorporate by reference their responses to each paragraph of
21 Plaintiff's Complaint as if fully set forth herein.

22 76. Defendants state that Celebrex® was and is safe and effective when used in
23 accordance with its FDA-approved prescribing information. Defendants state that the
24 potential effects of Celebrex® were and are adequately described in its FDA-approved
25 prescribing information, which was at all times adequate and comported with applicable
26

standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants are without knowledge or information sufficient to form a basis as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Negligence

79. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

80. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

1 81. Defendants state that Celebrex® was and is safe and effective when used in
2 accordance with its FDA-approved prescribing information. Defendants state that the
3 potential effects of Celebrex® were and are adequately described in its FDA-approved
4 prescribing information, which was at all times adequate and comported with applicable
5 standards of care and law. Defendants deny any wrongful conduct and deny the
6 remaining allegations in this paragraph of the Complaint.

7 82. Defendants are without knowledge or information sufficient to form a basis
8 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
9 deny the same. Defendants state that Celebrex® was and is safe and effective when used
10 in accordance with its FDA-approved prescribing information. Defendants state that the
11 potential effects of Celebrex® were and are adequately described in its FDA-approved
12 prescribing information, which was at all times adequate and comported with applicable
13 standards of care and law. Defendants deny any wrongful conduct and deny the
14 remaining allegations in this paragraph of the Complaint.

15 83. Defendants deny any wrongful conduct, deny that Celebrex® caused
16 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
17 Complaint.

18 **Response to Third Cause of Action: Breach of Implied Warranty**

19 84. Defendants incorporate by reference their responses to each paragraph of
20 Plaintiff's Complaint as if fully set forth herein.

21 85. Defendants are without knowledge or information sufficient to form a basis
22 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
23 deny the same. Defendants state that Celebrex® was and is safe and effective when used
24 in accordance with its FDA-approved prescribing information. Defendants state that the
25 potential effects of Celebrex® were and are adequately described in its FDA-approved
26 prescribing information, which was at all times adequate and comported with applicable

1 standards of care and law. Defendants admit that they provided FDA-approved
2 prescribing information regarding Celebrex®. Defendants deny the remaining allegations
3 in this paragraph of the Complaint.

4 86. Defendants are without knowledge or information sufficient to form a basis
5 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
6 deny the same. Defendants deny the remaining allegations in this paragraph of the
7 Complaint.

8 87. Defendants state that Celebrex® was and is safe and effective when used in
9 accordance with its FDA-approved prescribing information. Defendants state that the
10 potential effects of Celebrex® were and are adequately described in its FDA-approved
11 prescribing information, which was at all times adequate and comported with applicable
12 standards of care and law. Defendants deny the remaining allegations in this paragraph of
13 the Complaint.

14 88. Defendants deny any wrongful conduct, deny that Celebrex® caused
15 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
16 Complaint.

17 **Response to Fourth Cause of Action: Breach of Express Warranty**

18 89. Defendants incorporate by reference their responses to each paragraph of
19 Plaintiff's Complaint as if fully set forth herein.

20 90. Defendants are without knowledge or information sufficient to form a basis
21 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
22 deny the same. Defendants state that Celebrex® was and is safe and effective when used
23 in accordance with its FDA-approved prescribing information. Defendants state that the
24 potential effects of Celebrex® were and are adequately described in its FDA-approved
25 prescribing information, which was at all times adequate and comported with applicable
26 standards of care and law. Defendants admit that they provided FDA-approved

1 prescribing information regarding Celebrex®. Defendants deny the remaining allegations
2 in this paragraph of the Complaint.

3 91. Defendants are without knowledge or information sufficient to form a basis
4 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
5 deny the same. Defendants state that Celebrex® was and is safe and effective when used
6 in accordance with its FDA-approved prescribing information. Defendants state that the
7 potential effects of Celebrex® were and are adequately described in its FDA-approved
8 prescribing information, which was at all times adequate and comported with applicable
9 standards of care and law. Defendants admit that they provided FDA-approved
10 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct
11 and deny the remaining allegations in this paragraph of the Complaint.

12 92. Defendants deny any wrongful conduct, deny that Celebrex® caused
13 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
14 Complaint.

15 **Response to Fifth Cause of Action: Deceit by Concealment**

16 93. Defendants incorporate by reference their responses to each paragraph of
17 Plaintiff's Complaint as if fully set forth herein.

18 94. Defendants state that this paragraph of the Complaint contains legal
19 contentions to which no response is required. To the extent that a response is deemed
20 required, Defendants admit that they had duties as are imposed by law but deny having
21 breached such duties. Defendants state that Celebrex® was and is safe and effective when
22 used in accordance with its FDA-approved prescribing information. Defendants state that
23 the potential effects of Celebrex® were and are adequately described in its FDA-approved
24 prescribing information, which was at all times adequate and comported with applicable
25 standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

1 95. Defendants admit that, during certain periods of time, Pfizer and Pharmacia
2 co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare
3 providers who are by law authorized to prescribe drugs in accordance with their approval
4 by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
5 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
6 and distributed Celebrex® in the United States to be prescribed by healthcare providers
7 who are by law authorized to prescribe drugs in accordance with their approval by the
8 FDA. Defendants state that Celebrex® was and is safe and effective when used in
9 accordance with its FDA-approved prescribing information. Defendants state that the
10 potential effects of Celebrex® were and are adequately described in its FDA-approved
11 prescribing information, which was at all times adequate and comported with applicable
12 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex®
13 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of
14 the Complaint.

15 96. Defendants are without knowledge or information sufficient to form a basis
16 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
17 deny the same. Defendants state that Celebrex® was and is safe and effective when used
18 in accordance with its FDA-approved prescribing information. Defendants state that the
19 potential effects of Celebrex® were and are adequately described in its FDA-approved
20 prescribing information, which was at all times adequate and comported with applicable
21 standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 97. Defendants deny any wrongful conduct, deny that Celebrex® caused
24 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
25 Complaint.

26

Response to Sixth Cause of Action: Negligent Misrepresentation

98. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

99. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

100. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

1 103. Defendants are without knowledge or information sufficient to form a basis
2 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
3 deny the same. Defendants state that Celebrex® was and is safe and effective when used
4 in accordance with its FDA-approved prescribing information. Defendants state that the
5 potential effects of Celebrex® were and are adequately described in its FDA-approved
6 prescribing information, which was at all times adequate and comported with applicable
7 standards of care and law. Defendants deny any wrongful conduct and deny the
8 remaining allegations in this paragraph of the Complaint.

9 104. Defendants deny any wrongful conduct, deny that Celebrex® caused
10 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
11 Complaint.

12 **Response to Punitive Damage Allegations**
13 **(As to only the First, Second, Fifth, and Sixth Causes of Action)**

14 105. Defendants incorporate by reference their responses to each paragraph of
15 Plaintiff's Complaint as if fully set forth herein.

16 106. Defendants deny any wrongful conduct, deny that Celebrex® caused
17 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
18 Complaint.

19 107. Defendants are without knowledge or information sufficient to form a basis
20 as to the truth of the allegations regarding whether Plaintiff used Celebrex®, and therefore
21 deny the same. Defendants state that Celebrex® was and is safe and effective when used
22 in accordance with its FDA-approved prescribing information. Defendants state that the
23 potential effects of Celebrex® were and are adequately described in its FDA-approved
24 prescribing information, which was at all times adequate and comported with applicable
25 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex®
26

1 is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the
2 remaining allegations in this paragraph of the Complaint.

3 108. Defendants state that Celebrex® was and is safe and effective when used in
4 accordance with its FDA-approved prescribing information. Defendants state that the
5 potential effects of Celebrex® were and are adequately described in its FDA-approved
6 prescribing information, which was at all times adequate and comported with applicable
7 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex®
8 is defective, and deny the remaining allegations in this paragraph of the Complaint.

9 109. Defendants deny any wrongful conduct, deny that Celebrex® caused
10 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the
11 Complaint.

12 Answering the unnumbered paragraph following Paragraph 109 of the Complaint,
13 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
14 damage, and deny the remaining allegations in this paragraph of the Complaint, including
15 all subparts.

16 **III.**
17 **GENERAL DENIAL**

18 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's
19 Complaint that have not been previously admitted, denied, or explained.

20 **IV.**
21 **AFFIRMATIVE DEFENSES**

22 Defendants reserve the right to rely upon any of the following or additional
23 defenses to claims asserted by Plaintiff to the extent that such defenses are supported by
24 information developed through discovery or evidence at trial. Defendants affirmatively
25 show that:

First Defense

- 1
2 1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

3
4 2. Celebrex® is a prescription medical product. The federal government has
5 preempted the field of law applicable to the labeling and warning of prescription medical
6 products. Defendants' labeling and warning of Celebrex® was at all times in compliance
7 with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail
8 to state a claim upon which relief can be granted; such claims, if allowed, would conflict
9 with applicable federal law and violate the Supremacy Clause of the United States
10 Constitution.

Third Defense

11
12 3. At all relevant times, Defendants provided proper warnings, information and
13 instructions for the drug in accordance with generally recognized and prevailing standards
14 in existence at the time.

Fourth Defense

15
16 4. At all relevant times, Defendants' warnings and instructions with respect to
17 the use of Celebrex® conformed to the generally recognized, reasonably available, and
18 reliable state of knowledge at the time the drug was manufactured, marketed and
19 distributed.

Fifth Defense

20
21 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by
22 the applicable Statute of Limitations, and same is plead in full bar of any liability as to
23 Defendants.

Sixth Defense

- 24
25 6. Plaintiff's action is barred by the statute of repose.
26

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate her damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to the Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical

1 product, available only on the order of a licensed physician. Celebrex® provided an
2 adequate warning to Plaintiff's treating and prescribing physicians.

3 **Thirteenth Defense**

4 13. The product at issue was not in a defective condition or unreasonably
5 dangerous at the time it left the control of the manufacturer or seller.

6 **Fourteenth Defense**

7 14. Celebrex® was at all times material to the Complaint reasonably safe and
8 reasonably fit for its intended use and the warnings and instructions accompanying
9 Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally
10 adequate for its approved usages.

11 **Fifteenth Defense**

12 15. Plaintiff's causes of action are barred in whole or in part by the lack of a
13 defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with
14 the applicable standard of care.

15 **Sixteenth Defense**

16 16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or
17 abnormal use of the product Celebrex® after the product left the control of Defendants
18 and any liability of Defendants is therefore barred.

19 **Seventeenth Defense**

20 17. Plaintiff's alleged damages were not caused by any failure to warn on the
21 part of Defendants.

22 **Eighteenth Defense**

23 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or
24 subsequent conditions unrelated to Celebrex®.

25

26

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff are barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Arizona, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Arizona law.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Arizona. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v.*

1 *Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408
2 (2003).

3 **Thirty-ninth Defense**

4 39. The methods, standards, and techniques utilized with respect to the
5 manufacture, design, and marketing of Celebrex®, if any, used in this case, included
6 adequate warnings and instructions with respect to the product's use in the package insert
7 and other literature, and conformed to the generally recognized, reasonably available, and
8 reliable state of the knowledge at the time the product was marketed.

9 **Fortieth Defense**

10 40. The claims asserted in the Complaint are barred because Celebrex® was
11 designed, tested, manufactured and labeled in accordance with the state-of-the art industry
12 standards existing at the time of the sale.

13 **Forty-first Defense**

14 41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon
15 information and belief, such injuries and losses were caused by the actions of persons not
16 having real or apparent authority to take said actions on behalf of Defendants and over
17 whom Defendants had no control and for whom Defendants may not be held accountable.

18 **Forty-second Defense**

19 42. The claims asserted in the Complaint are barred, in whole or in part, because
20 Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for
21 which it was intended, and was distributed with adequate and sufficient warnings.

22 **Forty-third Defense**

23 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines
24 of laches, waiver, and/or estoppel.
25
26

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Plaintiff's claims are barred in whole or in part by the affirmative defenses referenced in A.R.S. § 12-683.

Fifty-sixth Defense

56. Defendants reserve the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

V.

JURY DEMAND

Defendants hereby demand a trial by jury.

VI.

PRAAYER

WHEREFORE, Defendants prays that Plaintiff take nothing by his suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which they may be justly entitled.

Dated: June 5, 2007

PERKINS COIE BROWN & BAIN P.A.

By s/ Christopher S. Coleman

Howard Ross Cabot

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Attorneys for Defendants

CERTIFICATE OF SERVICE

☒ I hereby certify that on June 5, 2007, I electronically transmitted the attached documents to the Clerk's Office using the ECF System for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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